UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION; STATE OF NEW YORK; STATE OF CALIFORNIA; STATE OF ILLINOIS; STATE OF NORTH CAROLINA; STATE OF OHIO; COMMONWEALTH OF PENNSYLVANIA; and COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v.

VYERA PHARMACEUTICALS, LLC; PHOENIXUS AG; MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC; and KEVIN MULLEADY, individually, as an owner and director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC,

Defendants.

Case No. 20-cv-00706 (DLC)

ECF Case

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS BY DEFENDANTS VYERA PHARMACEUTICALS, LLC AND PHOENIXUS AG

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INTRODUCTION

Through this litigation, the Federal Trade Commission ("FTC") and seven state Attorneys General (collectively with the FTC, "Plaintiffs") seek to expand antitrust law to prohibit certain commercial arrangements that they contend were designed to prevent generic competition to a drug sold under the brand name Daraprim.

Specifically, Plaintiffs allege that Vyera Pharmaceuticals, LLC, Phoenixus AG (together, "Vyera"), and two of Vyera's former executives, Martin Shkreli and Kevin Mulleady (collectively with Vyera, "Defendants"), implemented a three-part "scheme" to thwart the ability of generic manufacturers to obtain Food and Drug Administration ("FDA") approval to sell generic Daraprim.

First, Plaintiffs claim that Defendants restricted who was eligible to purchase Daraprim in order to prevent generic competitors from obtaining sufficient quantities to conduct FDA-required bioequivalence testing. Second, Plaintiffs claim that Defendants entered into exclusive supply agreements with two manufacturers of Daraprim's active pharmaceutical ingredient ("API"), pyrimethamine, with the alleged intent of keeping pyrimethamine out of the hands of generic competitors. Third, Plaintiffs claim that Vyera paid its distributors a fee to not sell sales data to third-party data aggregators, purportedly to deter generic competitors by concealing the market opportunity for generic Daraprim.

Notwithstanding these supposed obstacles, the Amended Complaint ("Complaint"), ECF No. 87, acknowledges that at least three manufacturers have filed applications with the FDA seeking approval of generic forms of Daraprim, and one such application has already been approved. Indeed, as the Complaint concedes, generic Daraprim is already available on the market today.

The Complaint fails to state a claim upon which relief can be granted for two principal reasons. First, as a threshold matter, the FTC and certain of the state Attorneys General lack the authority to bring this action in federal court. Second, even accepting Plaintiffs' allegations as true, the alleged conduct does not violate the antitrust laws.

The FTC and the individual state Attorneys General that have brought this action are executive law enforcement agencies with carefully defined powers conferred upon them by the legislative branches of the respective federal and state governments. In this action, however, the FTC and the Attorneys General of New York and Pennsylvania seek to bring litigation and to pursue remedies that exceed their defined scope of authority as reflected in plain and unambiguous statutory text.

In Section 13(b) of the Federal Trade Commission Act ("FTC Act"), Congress granted the FTC the limited authority to file suit in federal court only where the defendant "*is* violating" or "*is about to* violate" the law. The claims here relate solely to alleged acts undertaken in the past in connection with a single product (Daraprim) and a single course of conduct (claimed efforts to prevent generic competition to Daraprim). Since it is alleged that numerous manufacturers have already submitted generic applications, and that the FDA has already approved a generic form of Daraprim, there can be no allegation that Vyera "*is* violating" or "*is about to* violate" the law as required for the FTC to file suit in federal court under Section 13(b). For circumstances involving fully completed conduct, such as those alleged here, Congress has afforded the FTC a different venue and remedy: an administrative proceeding brought under FTC Act Section 5(b), which may be invoked where the defendant "*has been* or *is*" using an unfair method of competition.

The Pennsylvania Attorney General, too, brings claims beyond his limited mandate. The Pennsylvania Unfair Trade Practices and Consumer Protection Law parallels Section 13(b) in that

it permits the Attorney General to bring a cause of action only where the defendant "*is* using" or "*is about to* use" an unlawful trade practice. Moreover, that statute, by its plain terms and as construed by the Pennsylvania state courts, applies only to acts of fraud toward consumers and not to the antitrust claim asserted here. Pennsylvania has no antitrust statute.

The New York Attorney General likewise seeks to exceed her authority. In addition to a claim under the state antitrust statute, the Donnelly Act, which strictly caps financial penalties, New York asserts a claim under New York Executive Law Section 63(12). The Executive Law allows for broader remedies, but by its plain terms and legislative history applies only to present or future conduct that is "continu[ing]" or "carrying on," rather than past conduct.

Plaintiffs' lack of authority aside, the conduct alleged in the Complaint is not actionable for four distinct reasons: ***First***, Plaintiffs' theory that Vyera improperly restricted distribution to prevent generic competitors from obtaining sufficient quantities of Daraprim to conduct bioequivalence testing is premised on a legal fallacy. As the Supreme Court has recognized for over a century, a seller is free to choose with whom it does business and, subject to a single limited exception not applicable here, is under *no* obligation to deal with its competitors. ***Second***, the alleged contracts with two pyrimethamine API manufacturers are nothing more than exclusive supply agreements, which Plaintiffs correctly characterized to the Court during the initial pretrial conference as "common" in the pharmaceutical industry, and which courts in the Second Circuit recognize as procompetitive and presumptively lawful. If, as here, the exclusive contracts are of limited duration and do not substantially foreclose rivals from a relevant market (here, a market for pyrimethamine API), they do not violate the antitrust laws. ***Third***, Plaintiffs' allegations with respect to data sharing turn antitrust law on its head by seeking to impose liability based on a manufacturer's decision to *not* share pricing and sales data with its competitors. The law does not

require companies to share sales data with their rivals or allow their vendors to sell that data to others. Plaintiffs' theory that the alleged data sharing restrictions somehow harmed generic competition is also hopelessly implausible and internally inconsistent. ***Fourth***, insofar as Plaintiffs' claims are premised on an allegedly unlawful contract, combination, or conspiracy (as proscribed by Sherman Act Section 1 and analogous provisions of the state antitrust laws), those claims are not actionable because the Complaint does not allege facts to show that any of Vyera's counterparties to those contracts had the requisite intent to harm competition.

For all of these reasons, and as more fully described below, the Court should dismiss the Complaint in its entirety pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted.

BACKGROUND

I. The Product

Developed in 1953, Daraprim is used to treat an infection known as toxoplasmosis. Am. Compl. ¶¶ 75-76. From 2010 to 2015, Impax Laboratories, Inc. ("Impax") held the exclusive right to distribute Daraprim in the United States. *Id*. ¶¶ 82-85. During that time, Impax implemented a restricted distribution system and raised the price of Daraprim. *Id*. ¶ 85. Vyera[1] acquired the exclusive United States rights to Daraprim from Impax in 2015 and allegedly expanded Impax's distribution system to "improve distribution logistics." *Id*. ¶ 99. Vyera allegedly instituted a further price increase. *Id*. ¶¶ 87, 89. While the Complaint makes much of the amount of Vyera's price increase, Plaintiffs do not allege that the price increase itself was an antitrust violation.

[1] Although they are distinct legal entities, for simplicity, we refer to Phoenixus AG and Vyera Pharmaceuticals, LLC collectively as "Vyera." Phoenixus AG is a Swiss corporation based in Baar, Switzerland. Vyera Pharmaceuticals, LLC is a Delaware corporation with its principal place of business in New York City, and is a wholly-owned subsidiary of Phoenixus AG. *Id*. ¶¶ 24-26.

When Vyera acquired the rights to Daraprim in 2015, no pharmaceutical company was selling generic Daraprim. *Id.* ¶ 87. The central premise of the Complaint is that Vyera sought to preserve its exclusive position by blocking generic competition through its commercial agreements with its distributors and API suppliers, described above. *Id.* ¶¶ 4-7.

II. The Generic Drug Approval Process

New pharmaceutical drugs are required to undergo extensive testing to ensure their safety and efficacy. *Id.* ¶ 55. The Hatch-Waxman Act allows the FDA to approve abbreviated new drug applications ("ANDAs") for generic versions of previously approved brand drugs. *Id.* ¶¶ 54-55.

In order to obtain FDA approval, an ANDA applicant must meet a number of strict requirements intended to ensure that generic drugs are equally safe and effective as their brand name counterparts. *Id.* ¶ 56. Principally, the applicant must demonstrate that its proposed generic and the brand drug are bioequivalent, meaning that there are no significant differences in the rate and extent to which the drugs become available in the body. *Id.* ¶ 57. Demonstrating bioequivalence requires completing a rigorous testing process. *Id.* ¶ 58. Separately, the ANDA applicant must secure a safe and reliable source of FDA-approved API. *Id.* ¶ 62. As part of the ANDA process, the FDA closely scrutinizes the API manufacturer and will typically audit its facility. *Id.* The FDA's standards are exacting, and an ANDA applicant that fails to satisfy the FDA's rigorous requirements will be unable to secure approval to bring its generic drug to market. *See id.* ¶¶ 56-58.

III. The Allegations Regarding Vyera's Efforts To Prevent Generic Competition

The Complaint alleges that Defendants sought to prevent generic competition by: (1) selling Daraprim through a restricted distribution system that limited to whom Daraprim could be sold; (2) entering into exclusive supply agreements of limited duration with two suppliers of

pyrimethamine API; and (3) paying a fee to two of its distributors to maintain the confidentiality of Daraprim sales data and not sell it to data aggregating firms.

A. The Restricted Distribution System

Plaintiffs contend that Vyera used distribution restrictions to prevent generic manufacturers from obtaining sufficient quantities of Daraprim to conduct bioequivalence testing. *Id.* ¶ 99. The Complaint alleges that, shortly after acquiring the rights to Daraprim, Vyera *increased* to four the number of distributors that were eligible to sell Daraprim. *Id.* ¶¶ 99, 103. Each of these distributors is alleged to have been permitted to sell Daraprim, which was subject to restricted distribution even before Vyera acquired it, only to specific categories of buyers. *Id.* ¶¶ 83, 85, 104. For example, one of the distributors was assigned to sell Daraprim specifically to hospital and government purchasers, while another was assigned to sell Daraprim to pharmacies. *Id.* ¶¶ 105, 107. Vyera also allegedly imposed limits on the number of bottles of Daraprim that its distributors could sell to a single purchaser at any given time. *Id.* ¶ 125. Allegedly, none of the four distributors were permitted to sell Daraprim directly to a generic manufacturer without approval from Vyera. *Id.* ¶ 113. In addition to the alleged restrictions on the distributors themselves, the Complaint asserts that Vyera imposed resale restrictions that prevented hospitals and pharmacies that purchased Daraprim from Vyera's distributors from reselling it to generic manufacturers. *Id.* ¶¶ 114-18.

B. The Exclusive API Supply Agreements

The second aspect of the alleged scheme involved Vyera's entry into exclusive supply agreements of limited duration with two manufacturers of pyrimethamine API. *Id.* ¶ 144. The purpose of these exclusive supply agreements, according to the Complaint, was to prevent generic manufacturers from obtaining the pyrimethamine that they would need to secure FDA approval for generic Daraprim. *Id.* ¶ 148.

Vyera is alleged to have first approached two API manufacturers, Fukuzyu Pharmaceutical Co., Ltd. ("Fukuzyu") and Ipca Laboratories Ltd. ("Ipca"), in June 2015, shortly after it acquired Daraprim from Impax. *Id.* ¶ 149. Ipca responded that it could not supply pyrimethamine because, several months earlier, the FDA had banned Ipca from importing most of its APIs because of deficiencies in its manufacturing process. *Id.* ¶ 150. Following a series of negotiations, in January 2017, Vyera and Fukuzyu entered into a [redacted], which provides that Fukuzyu may sell pyrimethamine API for use within the United States only to Vyera. *Id.* ¶¶ 153-54.

The Complaint alleges that, in December 2017, Vyera entered into a similar agreement with another API manufacturer, RL Fine Chem ("RL Fine"). *Id.* ¶ 163. Although RL Fine had an approved API manufacturing process in Europe, that process did not comply with FDA requirements. *Id.* ¶¶ 160, 169. Even after entry into the supply agreement with Vyera, RL Fine did not "take any further steps to conform its process to FDA requirements." *Id.* ¶ 169. Vyera terminated its agreement with RL Fine in October 2019. *Id.* ¶ 172.

Plaintiffs allege that Fukuzyu and RL Fine were the "two most viable" suppliers of pyrimethamine. *Id.* ¶¶ 144, 173, 275. The Complaint does not allege, however, that there were no other manufacturers that produced or could produce pyrimethamine, or that generic companies could not have manufactured their own pyrimethamine API.

C. The Data Sharing Restrictions

The third and final aspect of the alleged scheme relates to Vyera's supposed efforts to "mask" the size of the Daraprim market in order to discourage generic entry. According to the Complaint, pharmaceutical distributors may choose to sell their sales data to third-party data aggregators, who in turn may sell that data to pharmaceutical manufacturers. *Id.* ¶ 178. Plaintiffs allege that Vyera included provisions in its agreements with two of its four distributors pursuant

to which Vyera agreed to pay a fee to the distributors in exchange for their agreement to maintain the confidentiality of Daraprim sales data.[2] *Id.* ¶ 183. The Complaint alleges that the purpose of the challenged provisions was to "obscure the size of the Daraprim market to make it less attractive to generic competitors." *Id.* ¶ 188.

Simultaneously, the Complaint alleges that Daraprim's pricing and sales volumes—the two data points that potential competitors would need to assess market opportunity—were widely known. As to pricing, the Complaint alleges that Vyera's price increases drew the attention of medical societies, patient advocacy organizations, the national news media, and even prompted a Congressional investigation. *Id.* ¶¶ 90, 138; *accord* ¶ 91 ("[T]he only person that didn't speak [out] against the price hike was the Pope." (further alteration omitted)). As to sales volume, the Complaint identifies Daraprim as the only FDA-approved treatment for toxoplasmosis, and states the annual number of toxoplasmosis cases per year in the United States. *Id.* ¶ 72.

The Complaint also alleges that, although Daraprim existed without generic competition for some six decades, it suddenly attracted a flurry of competitive activity, including from at least three generic manufacturers that filed ANDAs between 2014 and 2019. *Id.* ¶ 2. In fact, one of them is alleged to have "decided to pursue an ANDA for generic Daraprim . . . after seeing the publicity about Vyera's price increase." *Id.* ¶ 241.

IV. The Allegations Regarding Generic Competitors

The Complaint identifies four generic manufacturers whose efforts to obtain FDA approval for a generic form of Daraprim were allegedly hindered by Defendants' conduct: [redacted] ("[redacted]"), [redacted] ("[redacted]"), [redacted]

[2] The Complaint does not allege that Vyera's two other distributors were subject to such provisions. *Compare* Am. Compl. ¶ 103 (naming four distributors) *and* ¶ 190 (alleging the data provisions applied only to two of the four).

("[redacted]"), and Mylan, N.V. ("Mylan"). The Complaint ultimately admits that generic competitors were able to (1) obtain sufficient Daraprim samples to submit ANDAs; (2) secure their own API supplies; and (3) assess the market opportunity based on publicly available information, and ultimately were not prevented from seeking FDA approval to compete with Vyera. It also contains affirmative allegations that make clear that there were multiple reasons that had nothing to do with Defendants' alleged conduct why those would-be competitors were delayed in seeking FDA approval.

A. [redacted]

The Complaint alleges that, in 2013, [redacted] decided to develop a generic form of Daraprim. *Id.* ¶ 194. [redacted] secured Ipca as its API supplier and began bioequivalence testing with Ipca's pyrimethamine. *Id.* ¶¶ 198-99. In January 2015, however, the FDA banned Ipca from importing API, forcing [redacted] to find a new API supplier. *Id.* ¶ 200.

In 2016, [redacted] approached Fukuzyu, but Fukuzyu is alleged to have backed out of the parties' agreement for "economic reasons." *Id.* ¶¶ 201-02. [redacted], however, had a "backup plan," and secured [redacted] as its API supplier, even though the FDA had not concluded that [redacted] pyrimethamine manufacturing process conformed to FDA requirements. *Id.* ¶¶ 169, 203-04. After [redacted] informed the FDA of the change in its API supplier, in December 2017, the FDA directed [redacted] to redo its bioequivalence testing using [redacted] pyrimethamine. *Id.* ¶¶ 204-06. Although [redacted] allegedly had difficulty obtaining sufficient quantities of Daraprim to redo its bioequivalence testing, [redacted]. *Id.* ¶ 214.

On February 28, 2020, the FDA approved [redacted] ANDA and its generic Daraprim is now on the market. *Id.* ¶¶ 216, 218. The Complaint alleges that, absent Defendants' conduct, [redacted] likely would have launched its generic "in 2018 or earlier." *Id.* ¶ 219.

B. [redacted]

The second generic manufacturer identified in the Complaint is [redacted], which decided in [redacted] to develop a generic form of Daraprim. *Id.* ¶ 223. Like [redacted], [redacted] initially partnered with Ipca for its supply of pyrimethamine, but was forced to find a new supplier when the FDA banned Ipca from importing API. *Id.* ¶¶ 227-28. [redacted] turned next to [redacted], even though at no point had [redacted] conformed its pyrimethamine manufacturing process to FDA requirements. *Id.* ¶¶ 169, 230.

[redacted] submitted its ANDA to the FDA in [redacted] and immediately faced difficulties. *Id.* ¶¶ 231-32. In [redacted], the FDA provided a preliminary response to [redacted] ANDA, in which it required [redacted] to correct "several deficiencies," including those related to [redacted] API. *Id.* ¶ 232. Shortly thereafter, [redacted] backed out of its agreement with [redacted], requiring [redacted] to find another API supplier. *Id.* ¶¶ 232, 235. In [redacted], [redacted] entered into an API supply agreement with [redacted]. *Id.* ¶ 235.

[redacted] ANDA remains pending and, [redacted] *Id.* ¶ 237. The Complaint asserts that, absent Defendants' conduct, [redacted] could have launched its generic "in 2019 or earlier." *Id.* ¶ 238.

C. [redacted]

The third prospective generic competitor identified in the Complaint is [redacted]. *Id.* ¶ 239. The Complaint alleges that [redacted] decided to pursue a generic version of Daraprim in 2016 "after seeing the publicity about Vyera's price increase." *Id.* ¶ 241. [redacted] reached out to Fukuzyu in February 2016 seeking pyrimethamine, but Fukuzyu never responded. *Id.* ¶ 242. [redacted] turned next to API supplier [redacted] ("[redacted]"). *Id.* ¶ 243. It took [redacted] nearly three years to obtain FDA approval for its pyrimethamine manufacturing process. *Id.* ¶ 247.

[redacted]. *Id.* ¶ 260. Like [redacted], [redacted] allegedly faced difficulties obtaining sufficient quantities of Daraprim to conduct bioequivalence testing, [redacted]. *Id.* ¶ 259. Although [redacted] ANDA remains pending and its API supplier, [redacted], apparently did not gain FDA approval until [redacted], *id.* ¶ 247, Plaintiffs allege that [redacted] could have launched its generic "in 2018 or earlier" absent Defendants' conduct. *Id.* ¶ 261.

D. Mylan

The final generic manufacturer identified in the Complaint is Mylan. *Id.* ¶ 262. In 2015, Mylan allegedly "began considering developing a generic version of Daraprim." *Id.* ¶ 263. The allegations related to Mylan are confined to five paragraphs, and suggest that Mylan "analyzed" data on Daraprim sales and "inquired about" purchasing Daraprim. *Id.* ¶¶ 262-66. Mylan "abandoned" its efforts in [redacted], allegedly after concluding that Daraprim samples were "too difficult" to obtain and that it could not get a "real sense" of Daraprim's sales. *Id.* ¶ 266.[3]

[3] In addition to the four identified generic manufacturers, the Complaint also alleges that Vyera's conduct "likely impeded . . . at least one other generic company" whose identity is "not yet known." *Id.* ¶ 267.

V. The Allegations Regarding Submission And Approval Of ANDAs And "Likely" Recurrence

The Complaint alleges that four (and maybe five) generic manufacturers considered filing an ANDA for Daraprim, three successfully did so, and one of those ANDAs has already been approved, while the two others remain pending. Following the FDA's approval of [redacted] ANDA in February 2020, a generic form of Daraprim is now available on the market. *Id.* ¶¶ 216, 218.

Notwithstanding the fact that ANDAs have been submitted and that Daraprim already faces generic competition, the Complaint alleges that Vyera is "likely" to engage in similar conduct in the future. *Id.* ¶ 291 ("Defendants' anticompetitive conduct is likely to recur and cause additional harm to consumers."); *see also id.* ¶ 292 ("Absent relief, Vyera is likely to carry out a similar anticompetitive scheme with another drug."). The Complaint does not identify a drug for which Vyera could seek to delay generic competition, nor does it even allege that Vyera owns the rights to any other drugs.

VI. Procedural History

Following an investigation that began in 2015, the FTC and the New York Attorney General filed suit on January 27, 2020 against Vyera, Mr. Shkreli, and Mr. Mulleady.[4] *See* ECF No. 4. An amended complaint was filed on April 14, 2020, adding California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia as plaintiffs and asserting new claims under various state laws, but leaving the substantive allegations in the initial complaint essentially unchanged. *See* ECF No. 87.

[4] Mr. Shkreli founded Phoenixus AG and Vyera Pharmaceuticals, LLC. *Id.* ¶ 31. He formerly served as CEO of Vyera Pharmaceuticals, LLC. *Id.* Mr. Mulleady also formerly served as CEO of Vyera Pharmaceuticals, LLC for a period of time, and is currently the Chairman of the Board of Directors of Phoenixus AG. *Id.* ¶ 47.

Plaintiffs assert antitrust claims under Sherman Act Section 1 (Counts II and III), Sherman Act Section 2 (Count I), New York's Donnelly Act (Count IV A), California's Cartwright Act (Count V A), the Illinois Antitrust Act (Count VI), the North Carolina Unfair or Deceptive Practices Act (Count VII), Ohio's Valentine Act (Count VIII), Pennsylvania's common law restraint of trade doctrine (Count IX B), and the Virginia Antitrust Act (Count X). Four Attorneys General assert additional claims under their states' consumer protection laws: New York Executive Law Section 63(12) (Count IV B), the California Unfair Competition Act (Count V B), the North Carolina Unfair or Deceptive Practices Act (Count VII), and the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL") (Count IX A).

Vyera now moves to dismiss the Complaint in its entirety pursuant to Federal Rule of Civil Procedure 12(b)(6).

STANDARD OF REVIEW

To survive a motion to dismiss filed under Rule 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The plaintiff must plead "factual content" that "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While the Court is obliged to "accept as true the facts alleged in the Complaint" and to "draw[] all reasonable inferences in favor of the plaintiff," *Koch v. Christie's Int'l PLC*, 699 F.3d 141, 145 (2d Cir. 2012), the Court need not accept allegations that are wholly speculative, nor allegations that are "contradicted by other matters asserted . . . in drafting the complaint." *Fisk v. Letterman*, 401 F. Supp. 2d 362, 368 (S.D.N.Y. 2005).

ARGUMENT

I. The FTC Has Failed To Plead Facts Necessary To Invoke Its Limited Authority Under FTC Act Section 13(b)

"The [FTC] is an administrative body possessing only such powers as are granted by statute." *Arrow-Hart & Hegeman Elec. Co. v. FTC*, 291 U.S. 587, 598 (1934). Accordingly, its authority to bring suit and to seek remedies is expressly defined by Congress. *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 56 (2d Cir. 2006).

The FTC seeks to bring this action pursuant to the authority vested by Congress in Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). *See* Am. Compl. ¶ 15. Section 13(b) provides in relevant part as follows:

> Whenever the Commission has reason to believe . . . that any person, partnership, or corporation ***is violating***, or ***is about to violate***, any provision of law enforced by the Federal Trade Commission[,] . . . the Commission . . . may bring suit in a district court of the United States to enjoin any such act or practice.

15 U.S.C. § 53(b) (emphasis added). In other words, under the plain language of the statute, the FTC must plead facts demonstrating either an *ongoing* or *imminent* violation of law in order to bring an action in federal court.

Here, the FTC has done nothing of the sort. The FTC does not allege that Vyera "is" violating the law. Rather, it alleges that Vyera acted in the past to forestall competition to a drug that, as the Complaint acknowledges, has already been the subject of at least three ANDA submissions to the FDA and already faces generic competition. The FTC also does not allege that Vyera "is about to" violate the law, much less plead facts to support such a conclusion.

A. The FTC's Section 13(b) Authority To Seek Relief In Federal Court Is Expressly Limited To Instances Where The Defendant "Is Violating" Or "Is About To Violate" The Law

The Court's analysis may begin and end with the plain language of Section 13(b). "In determining the proper interpretation of a statute, this court will look first to the plain language

of a statute and interpret it by its ordinary, common meaning. If the statutory terms are unambiguous, our review generally ends and the statute is construed according to the plain meaning of its words." *Tyler v. Douglas*, 280 F.3d 116, 122 (2d Cir. 2001) (citations, internal quotation marks, and alteration omitted).

While the interpretation of Section 13(b)'s "about to violate" requirement presents a novel question in the Second Circuit, the Third Circuit's recent decision in *FTC v. Shire ViroPharma, Inc*. provides the roadmap. *See* 917 F.3d 147 (3d Cir. 2019). There, the FTC sought to invoke Section 13(b) to sue a drug manufacturer on grounds that the manufacturer delayed generic competition by making a series of allegedly frivolous filings with the FDA. *Id*. at 149. As here, the FTC alleged that the defendant's misconduct had occurred in the past and that the drug at issue already faced generic competition. *Id*. While the complaint made reference to what the defendant "could" do in the future, *id*. at 160, it did not allege facts suggesting that a violation was "about to" occur.

The FTC took the position that it need not allege that the past conduct was "about to" occur again, but could instead file an action under Section 13(b) so long as it could satisfy the traditional common law injunctive relief standard, which inquires simply as to whether there has been a past violation and whether there is a "reasonable likelihood that [the] past violation[] will recur." *Id*. at 156 (citing *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)).

The Third Circuit rejected the FTC's position as contrary to the plain language of Section 13(b) and affirmed the dismissal of the case, reasoning that the FTC had failed to allege facts sufficient to invoke its limited authority to bring a lawsuit in federal court:

> Section 13(b) requires that the FTC have reason to believe a wrongdoer "is violating" or "is about to violate" the law. . . . [T]his language is unambiguous; it prohibits existing or impending conduct. Simply put, Section 13(b) does not permit

> the FTC to bring a claim based on long-past conduct without some evidence that the defendant "is" committing or "is about to" commit another violation.

Shire ViroPharma, 917 F.3d at 156 (citation omitted).

The conclusion that Section 13(b) authorizes the FTC to seek relief in federal court only in cases where the defendant "is violating" or "is about to violate" the law is also compelled by the statutory structure of the FTC Act. Section 5 of the FTC Act proscribes "[u]nfair methods of competition in or affecting commerce." 15 U.S.C. § 45(a)(1). When faced with what it believes to be a violation of Section 5, the FTC may proceed in one of two ways, depending upon whether the alleged conduct occurred in the past, is still ongoing, or is about to happen. In cases of past or ongoing conduct, under FTC Act Section 5(b), the FTC may initiate administrative proceedings against a party that "***has been*** or ***is*** using" an unfair method of competition. 15 U.S.C. § 45(b) (emphasis added). In the case of ongoing or imminent future conduct, under Section 13(b), where the defendant "***is violating***, or ***is about to violate***" the law, the FTC may file suit in federal court seeking to enjoin the ongoing or imminent violation. 15 U.S.C. § 53(b) (emphasis added).

The *Shire ViroPharma* court recognized the evident distinction between Section 5(b) and Section 13(b). The court correctly rejected the FTC's warnings in that case that an adverse ruling would harm its ability to police misconduct, noting that the FTC's proper recourse in a case involving past conduct is to bring an administrative action under Section 5(b):

> The FTC's understandable preference for litigating under Section 13(b), rather than in an administrative proceeding, does not justify its expansion of the statutory language. If the FTC wants to recover for a past violation—where an entity "has been" violating the law—it must use Section 5(b). If the FTC instead chooses to use Section 13(b), it must plead that a violation of the law "is" occurring or "is about to" occur. Here, the FTC wants to use the most advantageous aspects of each statutory provision—to punish Shire for a past violation using the less onerous enforcement mechanism.

See Shire ViroPharma, 917 F.3d at 159 (citations omitted).

The legislative history of the FTC Act is consistent with the plain and unambiguous statutory language and squarely confirms that Congress intended Section 13(b) to provide the FTC with recourse in federal court only where the defendant is engaged in ongoing or imminent future misconduct. Before the enactment of Section 13(b) in 1973, the FTC lacked the authority to initiate a civil proceeding of any kind in federal court with respect to alleged anticompetitive conduct. Its only procedural option was an administrative proceeding brought under Section 5(b). *See United States v. JS & A Grp., Inc.*, 716 F.2d 451, 452 (7th Cir. 1983). Given the protracted nature of the administrative process, however, Section 5(b) was widely criticized at the time as being inadequate because it left the FTC without the ability to seek prompt recourse in cases involving ongoing or imminent harm to consumers.[5]

In 1973, Congress addressed this problem by enacting Section 13(b). *See* Pub. L. No. 93-153, § 408, 87 Stat. 576, 592 (1973). As explained in a preceding Senate report, "[t]he purpose of [Section 13(b)] is to permit the Commission to bring an immediate halt to unfair or deceptive acts or practices when . . . [a]t the present time such practices might continue for several years until agency action is completed." S. REP. NO. 93-151, at 30 (1973).[6]

Thus, the FTC Act's plain language, structure, and legislative history establish conclusively that the FTC has no authority to pursue a federal court action in connection with conduct that occurred solely in the past. *See FTC v. Credit Bureau Ctr., LLC*, 937 F.3d 764, 783 (7th Cir. 2019) ("Section 13(b) was designed to provide a remedy that ameliorates present or

[5] *See, e.g.*, David O. Bickart, *Civil Penalties under Section 5(m) of the Federal Trade Commission Act*, 44 U. CHI. L. REV. 761, 762-63 (1977).

[6] The FTC itself explained at the time that it sought the power to enjoin ongoing violations. *See* 119 CONG. REC. S21,445 (June 26, 1973) (letter from FTC General Counsel Ronald Dietrich to Sen. Henry Jackson explaining that, in Section 13(b), the FTC sought "the statutory authority to seek directly in the federal district courts preliminary injunctions against the continuance of anticompetitive conduct").

obviates the risk of future imminent harms, not a remedy that compensates for past violations." (citation and internal quotation marks omitted)).

B. The Complaint Alleges That The Conduct At Issue Occurred Solely In The Past

The Complaint makes plain that this is a case about an alleged *past* violation. It is not a case about a violation that "*is*" occurring or is "*about to*" occur for which the FTC might need to seek emergent relief. The claim here is that Defendants sought to prevent generic manufacturers from submitting ANDAs for Daraprim and from securing FDA approval to bring those generics to market. That is, by definition, past conduct because the Complaint also alleges that at least three generic manufacturers already submitted Daraprim ANDAs to the FDA, Am. Compl. ¶¶ 199, 231, 260, that one of those ANDAs has already been approved, *id*. ¶ 216, and that generic Daraprim is now on the market, *id*. ¶ 218. The FTC's own actions reinforce the conclusion that this case is solely about a past violation, and not about the need to seek emergent relief to stop some ongoing or imminent violation. The FTC began its investigation of the alleged misconduct in 2015, yet waited nearly *five years* to file its complaint—just as it did in *Shire ViroPharma*.

Perhaps recognizing the historical nature of the alleged conduct and the limitations of Section 13(b), the FTC speculates that it believes conduct is "*likely*" to occur in the future. *Id*. ¶ 291 ("Absent relief, Defendants' anticompetitive conduct is likely to recur and cause additional harm to consumers."), ¶ 292 ("Absent relief, Vyera is likely to carry out a similar anticompetitive scheme with another drug."). In doing so, the FTC seeks to recycle the same approach that the Third Circuit rejected in *Shire ViroPharma*. There, as here, the FTC sought to evade the plain language of Section 13(b)'s requirement that the defendant be "violating" or "about to violate" the law by seeking instead to meet the more lenient "likelihood of recurrence" standard for general injunctive relief. *See Shire ViroPharma*, 917 F.3d at 159 (discussing the "FTC's contention that Section 13(b)'s 'is violating' or 'is about to violate' language can be satisfied by showing a

violation in the distant past and a vague and generalized likelihood of recurrent conduct"). The Third Circuit correctly rejected the FTC's position as "distort[ing] Section 13(b) beyond its intended purpose." *Id*.

Not only has the FTC failed to plead that a future violation is "about to occur," but the Complaint affords ample grounds for the Court to conclude at the Rule 12 stage that there is no plausible basis to believe that a future violation even *could* occur. The FTC's allegations relate solely to one specific product (Daraprim) and one specific issue (supposed efforts to prevent generic manufacturers from obtaining FDA approval and bringing a Daraprim generic to market). There is no basis to conclude (and Plaintiffs have alleged no facts to support their conclusory speculation) that Vyera will take any future action to prevent generic competition to Daraprim, particularly given the allegations that numerous manufacturers have successfully submitted ANDAs and that Daraprim already faces generic competition.

Plaintiffs theorize that Vyera is "likely to carry out a similar anticompetitive scheme with another drug." Am. Compl. ¶ 292. But the Complaint does not identify the drug, nor does it even allege that Vyera *has* a drug for which it could possibly seek to prevent generic competition. Here, too, *Shire ViroPharma* is instructive. There, the FTC alleged that even though the drug at issue already faced generic competition, the defendant also held the rights to a different drug for which it "could" seek to delay generic competition. 917 F.3d at 153. The FTC went a step further in *Shire ViroPharma*, identifying the drug by name and alleging that the defendant had the "incentive to obstruct or delay competition to these or other products." *Id*. at 160 (citation omitted). The Third Circuit rejected the FTC's reliance on these allegations, however, because even though the defendant was alleged to have another drug for which it might seek to delay generic competition,

the Complaint "lack[ed] specific allegations that [the defendant] is 'about to violate' the law . . . as to [that drug]." *Id*.

The plain language of Section 13(b) requires that the defendant be "violating" or "about to violate" the law in order for the FTC to bring a lawsuit in federal court. Because the Complaint alleges no such thing, all of the FTC's claims (Counts I, II, and III) must be dismissed.[7]

II. The Attorneys General Of Pennsylvania And New York Similarly Lack Authority To Bring The Claims And To Seek The Remedies Asserted In The Complaint

Like the FTC, the Attorneys General of Pennsylvania and New York seek to bring claims beyond the scope of their legislative mandates, and to seek remedies to which they are not legally entitled.

A. The Pennsylvania Attorney General Cannot Bring Its UTPCPL Claim Because There Is No Allegation That Vyera "Is Using" Or "Is About To Use" An Unlawful Trade Practice And, In Any Event, The Claim Is Defectively Pleaded

"As a constitutional officer, the Attorney General has no inherent or implied powers; his powers are limited to those delegated to him by the people. . . . Those particular powers . . . are the *only* powers that the Attorney General may constitutionally exercise." *Commonwealth v.*

[7] Not only does the FTC seek to expand Section 13(b) to encompass conduct that neither "is" occurring, nor "is about to" occur, but it also seeks to read into Section 13(b) the right to pursue a remedy that is plainly unavailable under the statute—equitable monetary relief. *See* Am. Compl., Prayer for Relief ¶¶ 13-16. The FTC's pursuit of monetary relief runs directly counter to the text of Section 13(b), which provides that the *only* form of relief available under the statute is an injunction. Section 13(b) provides that when the defendant "is violating, or is about to violate" the law, the FTC "may bring suit in a district court of the United States ***to enjoin any such act or practice***." 15 U.S.C. § 53(b) (emphasis added). The statute makes no reference to any form of relief other than an injunction. *See Feins v. Am. Stock Exch., Inc.*, 81 F.3d 1215, 1221 (2d Cir. 1996) ("[W]here a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it." (citation omitted)). In its recent decision in *Credit Bureau Center*, the Seventh Circuit carefully analyzed Section 13(b) and concluded that, in line with the statutory text, it permits the FTC to seek only injunctive relief. 937 F.3d 764; *but see FTC v. Bronson Partners, LLC*, 654 F.3d 359, 365 (2d Cir. 2011) (reaching contrary conclusion, but without engaging in the analysis required by the Supreme Court in *Meghrig v. KFC Western, Inc.*, 516 U.S. 479 (1996)); *FTC v. Moses*, 913 F.3d 297, 309-10 (2d Cir. 2019) (following *Bronson*, without separately analyzing the issue). Thus, the FTC's pursuit of equitable monetary relief is plainly incompatible with the plain language of Section 13(b). Because the FTC does not have the authority to bring this action in federal court in the first place, and challenges to remedies are not required to be made at the Rule 12 stage, the Court need not address the scope of any remedy the FTC may seek. However, to the extent the FTC's claims are not dismissed, Vyera intends to challenge the FTC's right to pursue monetary relief in this litigation.

Goodman, 500 A.2d 1117, 1134 (Pa. Super. Ct. 1985) (Spaeth, P.J., concurring in part and dissenting in part). Like the FTC, the Pennsylvania Attorney General seeks to bring claims—and to pursue remedies—that exceed his expressly limited statutory authority.

The Pennsylvania Attorney General brings a claim under the Pennsylvania UTPCPL, 73 Pa. Cons. Stat. §§ 201-1 *et seq.*, which makes unlawful "[u]nfair methods of competition" and "unfair or deceptive acts or practices." *Id*. § 201-3. The UTPCPL uses a formulation that mirrors Section 13(b). It provides that the Attorney General "may bring an action" only where the defendant "***is using*** or ***is about to use*** any method, act or practice declared . . . to be unlawful." *Id*. § 201-4 (emphasis added). The plain language of the UTPCPL thus precludes the Pennsylvania Attorney General from bringing an action where, as here, the misconduct was allegedly completed in the past but is not ongoing or "about to" occur. *See supra* at 18-20.

Not only has the Pennsylvania Attorney General failed to allege that Vyera is "using" or "about to use" an unlawful practice, but he seeks to invoke the UTPCPL to police conduct and to recover remedies far beyond the scope of the statute. As Pennsylvania courts have recognized, the UTPCPL is fundamentally a consumer fraud statute. *See Feeney v. Disston Manor Pers. Care Home, Inc.*, 849 A.2d 590, 597 (Pa. Super. 2004) ("The general purpose of the UTPCPL is to protect the public from fraud and unfair or deceptive business practices.").

To that end, the UTPCPL defines the terms "[u]nfair methods of competition" and "unfair or deceptive acts or practices" with reference to twenty-one specific prohibited acts, including "[p]assing off goods or services as those of another" and making a "false or misleading representation of fact." 73 Pa. Cons. Stat. § 201-2(4)(i)-(xxi). The only prohibited act referenced in the Complaint—and the only one even conceivably applicable here—is the statute's "catchall" provision, which makes it unlawful to "[e]ngag[e] in any other fraudulent or deceptive conduct

which creates a likelihood of confusion or of misunderstanding." *Id*. § 201-(4)(xxi); Am. Compl. ¶ 350.

The Complaint alleges that Vyera sought to prevent generic competition to Daraprim. Lacking from the Complaint is *any* allegation of "fraudulent or deceptive conduct," much less conduct that "creates a likelihood of confusion or of misunderstanding."

Recent proceedings in the Pennsylvania state courts illustrate just how far afield the Attorney General strays in seeking to use the UTPCPL to police alleged antitrust violations that bear no connection to the perpetration of fraud on consumers. In *Anadarko Petroleum Corp. v. Commonwealth*, 206 A.3d 51 (Pa. Commw. Ct. 2019), the Attorney General brought claims under the UTPCPL against mineral mining firms alleging that they reached an anticompetitive agreement to divide the market for mineral leases in Pennsylvania. *Id*. at 53-54. The Commonwealth Court held that, insofar as the Attorney General's claim was predicated on an alleged anticompetitive agreement, it was not actionable under the UTPCPL. *Id*. at 60-61 ("[T]he Attorney General's claim that the mere existence of these business dealings created 'impairment of choice and the competitive process' is insufficient and does not . . . fit within any of the 21 categories of 'unfair methods of competition' or 'unfair or deceptive acts or practices' listed in [the UTPCPL]."). The Court held that the "only manner" in which the Attorney General could pursue alleged antitrust violations under the UTPCPL "is if they fit within one of the categories of behavior deemed . . . 'unfair methods of competition' or 'unfair or deceptive acts or practices.'" *Id*. at 60.[8]

It is not difficult to understand why the Attorney General strains to force the square peg of the Complaint's antitrust allegations into the round hole of the fraud-focused UTPCPL. While the

[8] The Pennsylvania Supreme Court subsequently granted a Petition for Allowance of Appeal and the parties are currently briefing the question presented of whether the Attorney General may "pursue antitrust remedies under the [UTPCPL]." *See Commonwealth v. Chesapeake Energy Corp.*, 218 A.3d 1205 (Pa. 2019) (per curiam).

UTPCPL affords the Attorney General the right to recover monetary damages, Pennsylvania's common law restraint of trade doctrine, under which the Attorney General also seeks to proceed, provides no such remedy. *XF Enters., Inc. v. BASF Corp.*, 47 Pa. D. & C. 4th 147, 150 (Pa. Ct. Com. Pl. 2000) (observing that "Pennsylvania common law lacks the damage provision necessary to give Pennsylvanians [a] cause of action" for monetary relief). "Pennsylvania is the *only* state that does not have an antitrust statute."[9]

The Pennsylvania General Assembly has determined, on twenty-four separate occasions, not to enact an antitrust statute to enable the Attorney General to pursue monetary relief against alleged antitrust violators. *Anadarko Petroleum Corp.*, 206 A.3d at 66 (Covey, J., concurring in part and dissenting in part). The Court should reject the transparent attempt here to override the Pennsylvania General Assembly and rewrite Pennsylvania law. *See Wallace v. Cutten*, 298 U.S. 229, 237 (1936) (Brandeis, J.) (the "enlargement" of "plain and ambiguous" statutory text "transcends the judicial function").

Because the Pennsylvania Attorney General has failed to plead facts actionable under the statute, the Court should dismiss its UTPCPL claim (Count IX A).

B. New York Executive Law Section 63(12) Authorizes The Attorney General To Seek Relief Only Where The Defendant Is Actively Continuing The Alleged Misconduct

Like the FTC and the Pennsylvania Attorney General, the New York Attorney General's powers are limited. "[T]he powers of the Attorney General are only those which are granted by [the] State Constitution and by enactments of [the] legislature." *People v. Dorsey*, 29 N.Y.S.2d 637, 643 (Queens Co. Ct. 1941).

[9] Dan Packel, *Pa. Sen. Proposes Antitrust Law As State Lags Behind Others*, LAW360 (Mar. 15, 2013), https://www.law360.com/competition/articles/424213/pa-sen-proposes-antitrust-law-as-state-lags-behind-others (emphasis added) (quoting a spokesman to the Pennsylvania Attorney General).

In addition to a claim under New York's antitrust statute, the Donnelly Act, the New York Attorney General seeks to bring a separate claim under New York Executive Law Section 63(12), which enables the Attorney General to pursue wrongdoers engaged in "persistent fraud or illegality in the carrying on, conducting or transaction of business." N.Y. Exec. Law § 63(12). While the Donnelly Act carries a statutory maximum financial penalty for corporations of $1 million, N.Y. Gen. Bus. Law § 341, Executive Law Section 63(12) contains no similar express limitation. The Executive Law provides in relevant part:

> Whenever any person ***shall engage*** in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply . . . for an order enjoining the ***continuance*** of such business activity or of any fraudulent or illegal acts, [and] directing restitution and damages . . . . The term "persistent fraud" or "illegality" as used herein shall include ***continuance or carrying on*** of any fraudulent or illegal act or conduct.

N.Y. Exec. Law § 63(12) (emphasis added).

Like FTC Act Section 13(b) and the Pennsylvania UTPCPL, the plain language of Section 63(12) establishes that the Legislature intended to confer on the Attorney General the narrow ability to seek injunctive relief under the statute where prompt relief is needed to stop ongoing misconduct. *See Abrams v. Magley*, 484 N.Y.S.2d 251, 253 (N.Y. App. Div. 1984) ("Section 63[12] was intended to prevent the perpetration of *ongoing* fraud or illegality . . . ." (emphasis added)).

Again, the Court's analysis may begin and end with the plain language of the statute. *See Tyler*, 280 F.3d at 122. As an initial matter, the circumstances in which the Attorney General can seek relief are limited to those in which any person "shall" engage in fraud or illegal acts. "Shall" is a "future-tense verb" meaning "[w]ill." BLACK'S LAW DICTIONARY (11th ed. 2019). Further, the principal form of relief available is "an order enjoining the *continuance* of such business activity or of any fraudulent or illegal acts." N.Y. Exec. Law § 63(12) (emphasis added). Finally,

the terms "persistent fraud" and "illegality" are defined to mean the "*continuance* or *carrying on*" of fraud or illegal conduct. *Id*. (emphasis added). The statute's plain terms thus speak solely in terms of the Attorney General's ability to seek relief where the defendant is *presently* engaged in fraud or illegality.

Section 63(12)'s legislative history confirms that the Attorney General's authority to invoke the statute is limited to situations in which the defendant is engaged in ongoing conduct. When the legislation came before the General Assembly in 1956, its primary sponsor explained that Section 63(12) "authorizes the Attorney General to enjoin the *continuation in business* . . . of persons who are guilty of repeated fraud or illegality." 1956 N.Y. Legislative Service Governor's Bill Jacket ch. 592 at 4 (emphasis added).

Because the Complaint alleges only fully completed conduct, rather than conduct that is "carrying on" or "continu[ing]," the Attorney General lacks the authority to bring suit under Section 63(12) and the New York Executive Law claim (Count IV B) must be dismissed.

III. Plaintiffs' Allegations Fail To State Cognizable Antitrust Claims Under Federal And State Law

Regardless of how the Court rules on the threshold question of whether the FTC and the Attorneys General of Pennsylvania and New York have the authority they seek to assert, the Complaint must be dismissed in its entirety because all Plaintiffs have failed to state a claim. The Complaint's allegations are wholly insufficient to state antitrust claims under settled federal and state precedent. Accordingly, those antitrust claims (Counts I, II, III, IV A, V A, VI, VII, VIII, IX B, and X) must be dismissed. And, the separate state consumer protection claims under the New York Executive Law (Count IV B), the California Unfair Competition Act (Count V B), the North Carolina Unfair or Deceptive Practices Act (Count VII), and the Pennsylvania UTPCPL (Count IX A) are expressly predicated on the same alleged conduct that forms the basis of the antitrust

claims.[10] Because that conduct cannot form the basis of an antitrust claim, the state consumer protection claims necessarily fail as well.[11]

A. Plaintiffs' Theories Of Restricted Distribution, Exclusive API Supply, And Data Restrictions Are Foreclosed As A Matter of Law

The Complaint describes three methods by which Defendants allegedly sought to delay generic competition to Daraprim: (1) the use of a restricted distribution system; (2) entry into exclusive supply agreements for pyrimethamine API; and (3) the payment of fees to two of Vyera's distributors to not sell sales data to third-party data aggregators. Even accepted as true, Plaintiffs' allegations fail to state a claim under settled federal antitrust law, and thus, all of their claims under the Sherman Act must be dismissed. And, because the New York Donnelly Act,[12] the California

[10] *See* Am. Compl. ¶ 328 (identifying Defendants' alleged violations of the Sherman Act and the Donnelly Act as the basis of the New York Executive Law claim), ¶ 333 (identifying the alleged distribution restrictions and exclusive API supply agreements as giving rise to the California Unfair Competition Act claim), ¶ 342 (alleging that the distribution restrictions, exclusive API supply agreements, and data sharing restrictions constitute "unfair methods of competition and/or unfair acts or practices" under the North Carolina Unfair or Deceptive Practices Act), ¶ 350 (alleging that the "aforesaid methods, acts, or practices" constitute "unfair methods of competition and/or unfair acts or practices" under the Pennsylvania UTPCPL). The case's procedural history perhaps explains why the alleged antitrust violations form the sole basis of the consumer protection claims. The initial complaint filed by the FTC and the New York Attorney General focused exclusively on alleged anticompetitive conduct. *See* ECF No. 4. The amended complaint added the California, North Carolina, and Pennsylvania consumer protection claims, but made virtually no change to the substantive allegations from the initial complaint. *See* ECF No. 87.

[11] Indeed, courts in those jurisdictions routinely dismiss tag-along consumer protection claims where, as here, those claims are predicated on conduct that does not constitute a violation of the antitrust laws. *See, e.g.*, *Eastman v. Quest Diagnostics Inc.*, 108 F. Supp. 3d 827, 838 (N.D. Cal. 2015) (dismissing California Unfair Competition Act claim on grounds that it was "derivative" of accompanying Sherman Act and Cartwright Act claims for which the plaintiff failed to state a claim). To the extent that New York, California, North Carolina, or Pennsylvania were to contend that their consumer protection claims arise on some other grounds, there would be no independent basis for such a claim to be brought in federal court. Thus, once the Court dismisses Plaintiffs' claims under federal law, it should decline to exercise pendant jurisdiction and dismiss Plaintiffs' state law claims as well. *See, e.g.*, *Weathers v. Millbrook Cent. Sch. Dist.*, 486 F. Supp. 2d 273, 276 (S.D.N.Y. 2007) ("[W]hen 'all federal-law claims are eliminated before trial, the balance of factors to be considered under the pendent jurisdiction doctrine—judicial economy, convenience, fairness, and comity—will point toward declining to exercise jurisdiction over the remaining state-law claims.'" (quoting *Carnegie–Mellon Univ. v. Cohill*, 484 U.S. 343, 350 n.7 (1988))).

[12] *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 260 (S.D.N.Y. 2019) ("[T]he Donnelly Act—often called a 'Little Sherman Act'—should generally be construed in light of Federal precedent." (quoting *Anheuser-Busch, Inc. v. Abrams*, 520 N.E.2d 535, 539 (N.Y. 1988))).

Cartwright Act,[13] the Illinois Antitrust Act,[14] the North Carolina Unfair or Deceptive Practices Act,[15] the Ohio Valentine Act,[16] the Pennsylvania common law restraint of trade doctrine,[17] and the Virginia Antitrust Act[18] are each construed in accordance with federal antitrust precedent, those claims must be dismissed for the same reasons.

1. The Allegations Regarding Vyera's Restricted Distribution System Are Not Actionable Because Vyera Was Under No Obligation To Sell Daraprim To Its Competitors

At its core, Plaintiffs' theory is that Vyera imposed contractual restrictions on its distributors to "prevent[] generic companies from purchasing Daraprim" and to "deny[] them the ability to conduct the bioequivalence testing necessary for FDA approval." Am. Compl. ¶ 99. But Plaintiffs' theory relies on a fundamental misconception: it incorrectly presupposes that Vyera was under an obligation to sell Daraprim to its competitors when, in fact, no such obligation exists.

Subject to a narrow exception not applicable here, "the Sherman Act 'does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely

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[13] *In re High-Tech Emp. Antitrust Litig.*, 856 F. Supp. 2d 1103, 1114 (N.D. Cal. 2012) ("[T]he analysis under California's antitrust law mirrors the analysis under federal law because the Cartwright Act was modeled after the Sherman Act." (quoting *County of Tuolumne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1160 (9th Cir. 2001))).

[14] *McGarry & McGarry, LLC v. Bankr. Mgmt. Sols., Inc.*, 937 F.3d 1056, 1062 (7th Cir. 2019) ("The [Illinois Antitrust] Act expressly requires harmonization with federal antitrust law as interpreted by the federal courts, so Illinois courts interpret the state antitrust law in harmony with federal case law construing analogous provisions of federal legislation." (citation, internal quotation marks, and alterations omitted)).

[15] *Microsoft Corp. v. Comput. Support Servs. of Carolina, Inc.*, 123 F. Supp. 2d 945, 955 (W.D.N.C. 2000) ("[B]ecause the North Carolina antitrust statutes track the language of the Sherman Act, the North Carolina Supreme Court has described the Sherman Act as 'instructive in determining the full reach' of the statutes." (quoting *Rose v. Vulcan Materials Co.*, 194 S.E.2d 521, 530 (N.C. 1973))).

[16] *Johnson v. Microsoft Corp.*, 834 N.E.2d 791, 794-95 (Ohio 2005) ("[T]he Ohio General Assembly patterned Ohio's antitrust provisions in accordance with federal antitrust provisions. . . . Due to the similarity of these provisions, Ohio has long followed federal law in interpreting the Valentine Act.").

[17] *Yeager's Fuel, Inc. v. Pa. Power & Light Co.*, 953 F. Supp. 617, 668 (E.D. Pa. 1997) (analysis of Pennsylvania common law restraint of trade claims "mirrors" analysis under the Sherman Act).

[18] Va. Code Ann. § 59.1-9.17 (the Virginia Antitrust Act "shall be applied and construed to effectuate its general purposes in harmony with judicial interpretation of comparable federal statutory provisions"); *accord Oksanen v. Page Mem'l Hosp.*, 945 F.2d 696, 710 (4th Cir. 1991) ("The Virginia Antitrust Act . . . shares common elements with sections one and two of the Sherman Act.").

to exercise his own independent discretion as to parties with whom he will deal.'" *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) (quoting *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919)); *see also Oreck Corp. v. Whirlpool Corp.*, 579 F.2d 126, 133 (2d Cir. 1978) ("It has always been the prerogative of a manufacturer to decide with whom it will deal.").[19]

There is one narrow exception to the right of a manufacturer to freely choose with whom it will deal that "comes into play only when a monopolist seeks to terminate a prior (voluntary) course of dealing with a competitor." *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134 (2d Cir. 2014) (citation and internal quotation marks omitted); *accord Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 603 (1985) (liability for refusing to deal with a competitor may arise only where "the monopolist elected to make an important change in a pattern of distribution that had originated in a competitive market and had persisted for several years"). As the Supreme Court has observed, this is the sole exception, and courts have been "very cautious" about recognizing others. *Trinko*, 540 U.S. at 408.

There is no allegation that Vyera had any obligation to sell Daraprim to any prospective generic manufacturer that wished to compete with Vyera, nor that Vyera had a prior course of dealing with any generic manufacturer that could conceivably give rise to such an obligation. In fact, the Complaint pleads facts suggesting that the distribution restrictions that are alleged to have prevented generic manufacturers from obtaining Daraprim were put in place long before Vyera even acquired the rights to Daraprim in 2015. *See* Am. Compl. ¶ 83 (alleging that, between 2010

[19] That Vyera cannot be forced to sell its product to its direct competitors is not a controversial proposition. In fact, in the "Tips & Advice" portion of its website, the FTC states: "Limitations on how or where a dealer may sell a product (that is, customer or territory restrictions) are generally legal — if they are imposed by a manufacturer acting on its own." *See Tips & Advice, Dealings in the Supply Chain: Manufacturer-imposed Requirements*, FEDERAL TRADE COMMISSION, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-supply-chain/manufacturer-imposed (last visited May 20, 2020) (emphasis omitted).

and 2015, a prior owner of Daraprim, Amedra Pharmaceuticals LLC ("Amedra"), "developed a plan to remove Daraprim from normal distribution channels and put it into a restricted distribution system"), ¶ 85 (alleging that, after acquiring Daraprim from Amedra, Impax "began to implement Amedra's restricted distribution system"). The Complaint alleges that not only did Vyera "inherit[]" the restricted distribution system, but it actually "*expand[ed]* the number of distributors to improve distribution logistics." *Id*. ¶ 99 (emphasis added). That is the opposite of the narrow exception recognized by the Second Circuit in *Adderall XR Antitrust Litigation* and by the Supreme Court in *Aspen Skiing*.

While it is true that the Complaint alleges that Vyera not only refused to sell Daraprim to its direct competitors itself but imposed downstream restrictions on its distributors as well (*see, e.g.*, Am. Compl. ¶ 104), for purposes of the antitrust laws, this is a distinction without a difference. The right of a manufacturer to do business with buyers of its own choosing remains the same whether the manufacturer makes sales directly or does so through a distributor.

The Second Circuit's holding in *E & L Consulting, Ltd. v. Doman Industries Ltd.*, 472 F.3d 23 (2d Cir. 2006), makes this point. There, the plaintiff challenged a distributorship agreement between a monopolist lumber supplier and its exclusive distributor, alleging that the exclusive distributorship resulted in fewer available sellers. *Id*. at 29-30. The Second Circuit affirmed the Rule 12 dismissal of the claims, reasoning that the supplier's decision to conduct its sales through a distributor achieved the same end result as if the supplier had conducted the sales on its own. *Id*. at 29 (the distributorship agreement "provides no monopolistic benefit to [defendant] that it does not already enjoy and would not continue to enjoy if the exclusive distributorship were enjoined. To put it another way, had [defendant] established its own in-house distribution system with the

same monopoly that [the distributor] is alleged to possess, there would have been no increase in the restriction of output of green hem-fir lumber . . .").

Plaintiffs' failure to allege a cognizable duty of Vyera to sell Daraprim to its competitors requires dismissal of their antitrust claims regardless of whether they are alleged to arise under a theory of an unlawful contract, combination, or conspiracy (i.e., Sherman Act Section 1), or a theory of monopolization (i.e., Sherman Act Section 2). Indeed, courts routinely grant Rule 12 motions on precisely these grounds. *See, e.g.*, *Trinko*, 540 U.S. at 411 (affirming dismissal of Section 2 monopolization claims on grounds that "there is no duty to aid competitors"); *Cinema Vill. Cinemart, Inc. v. Regal Entm't Grp.*, No. 15-cv-5488, 2016 WL 5719790, at *3 (S.D.N.Y. Sept. 29, 2016) (dismissing Section 1 conspiracy claims on grounds that a private party "generally has a right to deal, or refuse to deal, with whomever it likes, as long as it does so independently" (quoting *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 761 (1984))), *aff'd*, 708 F. App'x 29 (2d Cir. 2017).[20]

2. Vyera's Agreements With Fukuzyu And RL Fine Constitute Presumptively Lawful, Procompetitive Exclusive Supply Agreements

The Complaint next turns to the theory that Vyera sought to keep pyrimethamine, the active ingredient in Daraprim, out of the hands of generic competitors by entering into exclusive agreements with the two supposedly "most viable" pyrimethamine suppliers, Fukuzyu and RL

[20] *See also Adderall XR Antitrust Litig.*, 754 F.3d at 136 (affirming dismissal of Sherman Act claims on grounds that the plaintiff "failed to allege facts that would place this case within [the] narrow exception to the long recognized right of a trader or manufacturer . . . freely to exercise his own independent discretion as to parties with whom he will deal" (citation, internal quotation marks, and alteration omitted)); *In re Elevator Antitrust Litig.*, 502 F.3d 47, 54 (2d Cir. 2007) (per curiam) ("The . . . claims in this case do not fall within the sole exception to the right of refusal to deal: the complaint does not allege that defendants terminated a prior relationship . . . which . . . could evince monopolistic motives."); *Eatoni Ergonomics, Inc. v. Research In Motion Corp.*, 826 F. Supp. 2d 705, 709 (S.D.N.Y. 2011) (dismissing antitrust claims on grounds that the defendant's refusal to deal with a competitor was "within the bounds of lawful business conduct" because the parties did not have a prior profitable course of dealing).

Fine.[21] Am. Compl. ¶ 144. However, as Plaintiffs acknowledged during the parties' Rule 16 conference, exclusive supply agreements are common in the pharmaceutical industry, where drug manufacturers must ensure safe, reliable sources of API to avoid supply chain disruption and drug shortages.[22] Exclusive supply agreements are not only common, but as courts have long recognized, they "have pro-competitive purposes and effects, such as assuring steady supply, affording protection against price fluctuations, reducing selling expenses, and promoting stable, long-term business relationships." *Geneva Pharm. Tech. Corp.*, 386 F.3d at 508 (citing *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 333-35 (1961)). Exclusive supply agreements are thus "presumptively legal." *CDC Techs., Inc. v. IDEXX Labs., Inc.*, 186 F.3d 74, 80 (2d Cir. 1999) (citation omitted); *accord United States v. Microsoft Corp.*, 253 F.3d 34, 69 (D.C. Cir. 2001) ("Permitting an antitrust action to proceed any time a firm enters into an exclusive deal would both discourage a presumptively legitimate business practice and encourage costly antitrust actions."). This presumption of legality applies with equal measure to claims arising under a theory of an unlawful contract, combination, or conspiracy, and those arising under a theory of unlawful monopolization. *See, e.g.*, *Elecs. Commc'ns Corp. v. Toshiba Am. Consumer Prod., Inc.*, 129 F.3d 240, 246 (2d Cir. 1997).

"Exclusive dealing is an unreasonable restraint of trade . . . only when the agreement freezes out a significant fraction of buyers or sellers from the market." *Geneva Pharm. Tech. Corp.*, 386 F.3d at 508. Central to the assessment of an exclusive dealing agreement's ability to freeze out competition is "the duration and terminability of the arrangement." *Mazda v. Carfax,*

[21] An agreement pursuant to which a supplier pledges to sell only to one particular buyer is referred to as an exclusive supply agreement. *See Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 491 (2d Cir. 2004).

[22] *See* ECF No. 88, Tr. of Mar. 20, 2020 Pretrial Telephone Conference at 17-18 (Counsel to the FTC: "It's not uncommon in the pharmaceutical industry for a branded company to enter an exclusive contract with an API supplier in order to make sure that it has adequate supply and that their interests are aligned.").

Inc., No. 13-cv-2680, 2016 WL 7231941, at *5 (S.D.N.Y. Dec. 9, 2016) (citation omitted), *aff'd sub nom. Maxon Hyundai Mazda v. Carfax, Inc.*, 726 F. App'x 66 (2d Cir. 2018). "Short-term or at-will exclusive dealing contracts generally do not threaten competition because when they expire, a firm's rivals can bid to take over the contract." *Id*. (citing *CDC Techs.*, 186 F.3d at 81). Such agreements "encourage, rather than discourage, competition, because the incumbent and [its competitors] have a strong incentive continually to improve the [quality] and prices they offer in order to secure the exclusive positions." *Balaklaw v. Lovell*, 14 F.3d 793, 799 (2d Cir. 1994).

Plaintiffs' allegations fall far short of overcoming the presumptive legality of exclusive supply arrangements. As an initial matter, the Complaint fails to plausibly allege that Vyera's exclusive supply agreements with Fukuzyu and RL Fine were even capable of freezing out generic competition. *See Xerox Corp. v. Media Scis. Int'l, Inc.*, 511 F. Supp. 2d 372, 389 (S.D.N.Y. 2007) ("To state a claim for exclusive dealing, [plaintiff] must allege as a threshold matter . . . a substantial foreclosure of competition in the relevant market." (citation and internal quotation marks omitted)). The Complaint conclusorily asserts that Fukuzyu and RL Fine were the two "most viable" pyrimethamine suppliers. Am. Compl. ¶¶ 144, 173, 275.[23] But, the Complaint does not allege that there were no other manufacturers capable of supplying pyrimethamine, or that prospective generic competitors were incapable of manufacturing their own pyrimethamine API.[24] In fact, the Complaint identifies by name at least three other API manufacturers that either had

[23] These conclusory allegations need not be credited in the context of this motion to dismiss given the inconsistent allegation that RL Fine never "conform[ed] its [pyrimethamine manufacturing] process to FDA requirements." *See* Am. Compl. ¶¶ 160, 169; *see also Fisk*, 401 F. Supp. 2d at 368. If Plaintiffs' relevant market for purposes of assessing foreclosure with respect to pyrimethamine API includes companies like RL Fine, which had not yet conformed its process to FDA requirements, then it must include the many other API manufacturers and generic drug companies that also had, or could develop, their own processes for producing pyrimethamine API.

[24] *See* Am. Compl. ¶ 62 (noting only that "[p]harmaceutical companies *typically* purchase API from third-party suppliers" (emphasis added)).

already submitted a drug master file[25] for the production of pyrimethamine with the FDA, or were in the process of doing so. *Id.* ¶ 149 (Ipca), ¶ 235 ([redacted]), ¶ 243 ([redacted]). As courts recognize, exclusive dealing agreements cannot harm competition if they affect only a subset of participants within a product market. *See Wellnx Life Scis. Inc. v. Iovate Health Scis. Research Inc.*, 516 F. Supp. 2d 270, 293 (S.D.N.Y. 2007) (dismissing exclusive dealing claims on grounds that the alleged arrangement left numerous "other competitors [to] compete unobstructed").

The alleged agreements with Fukuzyu and RL Fine also cannot form the basis of viable exclusive dealing claims because, as alleged, they were of short duration and were easily terminable. The Complaint alleges that Vyera's exclusive supply agreement with Fukuzyu had an initial term of just [redacted]. Am. Compl. ¶ 153. Courts routinely reject exclusive dealing claims on grounds that such short-term contracts do not adversely affect competition. *See, e.g.*, *Spinelli v. Nat'l Football League*, 96 F. Supp. 3d 81, 117 (S.D.N.Y. 2015) (granting a motion to dismiss on grounds that three-year exclusive dealing agreements "do not foreclose competition and are not anticompetitive as a matter of law"); *see also Balaklaw*, 14 F.3d at 800 (affirming the entry of summary judgment for the defendant against exclusive dealing claims on grounds that a three-year exclusive arrangement posed no threat of "adverse economic consequences" (citation omitted)); *Pro Search Plus, LLC v. VFM Leonardo, Inc.*, No. 12-cv-2102, 2013 WL 3936394, at *4 (C.D. Cal. July 30, 2013) (dismissing exclusive dealing claims on grounds that exclusive agreements ranging from two to five years are of such short duration that they "can promote competition" (emphasis omitted)). The Complaint does not allege the duration of Vyera's exclusive supply agreement with RL Fine, but it does allege that Vyera terminated that agreement less than two

[25] *See id.* ¶ 64 ("A supplier that has already developed a process to produce an API can separately submit a drug master file . . . to the FDA containing this required information.").

years after its execution. Am. Compl. ¶ 172. Because of their limited potential to harm competition, courts recognize that readily terminable exclusive agreements of this sort are not actionable under the antitrust laws. *See CDC Techs.*, 186 F.3d at 81.

3. Plaintiffs' Data Sharing Theory Is Incompatible With Antitrust Precedent And, In Any Event, Plaintiffs' Allegations Of Harm To Competition Are Implausible

The Complaint's third and final theory is that Vyera entered into agreements with two of its four distributors that kept them from selling sales and pricing data to third-party data aggregators, who in turn could have sold that data to prospective generic entrants. According to the Complaint, Vyera did so with the aim of "masking the true size of the Daraprim market to deter generic competitors." Am. Compl. ¶ 93.

As an initial matter, it is odd that Plaintiffs would challenge a decision by a manufacturer to *not* permit the divulgence of its competitively sensitive pricing and sales data to its competitors. After all, a far more common theory in antitrust cases is that the sharing of such information among competitors facilitates price fixing and other forms of anticompetitive collusion. *See, e.g.*, *In re London Silver Fixing, Ltd., Antitrust Litig.*, 332 F. Supp. 3d 885, 904 (S.D.N.Y. 2018) ("To state the obvious, it is not rational for horizontal competitors to share current pricing information absent the existence of an anticompetitive agreement."). Certainly, the Complaint does not allege that would-be generic competitors had any independent right to that information. Nor do Plaintiffs allege that Vyera's distributors were required to sell it to third-party aggregators (who could then sell it to others) or were not permitted to charge Vyera a fee in order to maintain that data in confidence.

Plaintiffs' novel theory is not only curious, but it is also facially implausible. To survive a Rule 12 motion, the claim asserted must be one that is at least "plausible" in light of the factual

allegations.[26] *Twombly*, 550 U.S. at 570. Assessing plausibility is a "context-specific task," requiring the application of "judicial experience and common sense." *Iqbal*, 556 U.S. at 679. Accordingly, the Court should reject allegations that are facially implausible or directly at odds with other allegations in the Complaint. *Fisk*, 401 F. Supp. 2d at 368; *accord U.S. Bank Nat'l Ass'n v. Bank of Am., N.A.*, No. 12-cv-4873, 2012 WL 6136017, at *7 (S.D.N.Y. Dec. 11, 2012) ("Where plaintiff's own pleadings are internally inconsistent, a court is neither obligated to reconcile nor accept the contradictory allegations in the pleadings as true in deciding a motion to dismiss." (citation omitted)).

Plaintiffs' assertion that Vyera hindered generic competition by paying fees to two of its four distributors to maintain the confidentiality of Daraprim sales data by not selling it to third-party data aggregators is both facially implausible and directly contradicted by other allegations in the Complaint. On the one hand, the Complaint asserts: "Absent these . . . agreements, which distorted Daraprim's reported sales revenues, Mylan and other pharmaceutical companies would have known that Daraprim revenues had grown substantially due to Vyera's 4,000% price increase, and thus offered a lucrative competitive opportunity." Am. Compl. ¶ 276.

On the other hand, the Complaint alleges that information about the price and volume of Daraprim sales—the only two metrics conceivably relevant to assessing the market opportunity—were readily available.

[26] Plaintiffs appear to allege that the data agreements violate only certain of the relevant statutes, but not others. For example, Count I (Sherman Act Section 2) purports to apply broadly with respect to all alleged conduct. *See* Am. Compl. ¶¶ 314-18. Counts II and III (Sherman Act Section 1), in contrast, specifically identify, respectively, the distribution restrictions and the exclusive API supply agreements, but do not include the data sharing agreements. *See id*. ¶¶ 319-20, 321-22. Indeed, the states appear to disagree as to whether these alleged agreements can support an antitrust claim; Illinois and North Carolina identify the data agreements as violating their respective statutes, *id*. ¶¶ 336, 339, but the remaining states' claims make no mention of the data agreements. In any event, as the Second Circuit has explained with respect to the applicable pleading standard, the Court "need not draw fine lines" because "our precedents support application of *Twombly* to . . . claims asserted under both Section 1 and Section 2." *Elevator Antitrust Litig.*, 502 F.3d at 50.

As to price, the Complaint alleges that the Daraprim price increases were so widely known that they were the subject of national news coverage, congressional hearings, and widespread public backlash. *Id.* ¶ 90 ("Vyera swiftly faced outcries from health care providers, patients, medical societies, the general public, and Congress"), ¶ 138 (describing coverage of the price increases in *The New York Times*). In the words of the Complaint, "the only person that didn't speak [out] against the price hike was the Pope." *Id.* ¶ 91 (further alteration omitted). As to volume, the Complaint alleges that Daraprim was on the market for decades with no therapeutic alternative, *id.* ¶ 308, suggesting that historical data on annual sales would have been readily accessible and relevant to assessing the generic opportunity. In fact, the Complaint specifically alleges the average number of annual toxoplasmosis cases (for which Daraprim was therapeutically indicated) in the United States from 2003 to 2012. *Id.* ¶ 72.

Plaintiffs' theory that Vyera succeeded in "masking" the market opportunity for Daraprim is undermined further by their allegations regarding the state of the market before and after the alleged price increases. As alleged, Daraprim was available for more than sixty years without generic competition. *Id.* ¶ 2. However, as soon as Impax and Vyera increased Daraprim's price, Daraprim attracted a flurry of competitive activity, including from at least three generic manufacturers that filed ANDAs between 2014 and 2019. *Id.* ¶¶ 199, 231, 260. And, one of those manufacturers, [redacted], is expressly alleged to have "decided to pursue an ANDA . . . after seeing the publicity about Vyera's price increase." *Id.* ¶ 241. In light of the allegations making plain that generic manufacturers were well aware of the market opportunity and, in fact, submitted ANDAs because of it, the theory that data agreements with two of Vyera's four distributors hindered generic competition is implausible and cannot sustain Plaintiffs' claims.

4. Whether Viewed Individually Or Collectively, Plaintiffs' Theories Fail To State A Claim

From the start, Plaintiffs seek to paint the allegations of restricted distribution, exclusive API supply agreements, and data sharing agreements as part of a "comprehensive scheme." Am. Compl. ¶ 1; *see also id*. ¶ 3 (describing an "elaborate, multi-part scheme"). The aim, it appears, is to encourage a collective focus rather than a focus on any one individual act. *See City of Mishawaka, Ind. v. Am. Elec. Power Co.*, 616 F.2d 976, 986 (7th Cir. 1980) (describing the plaintiff's attempt to "mix . . . the various ingredients of . . . behavior in a monopoly broth that produces [an] unsavory flavor").

Defendants do not dispute that the Complaint should be read "without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962). However, as the Second Circuit has long recognized, a plaintiff cannot state an antitrust claim merely by combining multiple acts, each of which standing alone is not actionable. *See Eatoni Ergonomics, Inc. v. Research in Motion Corp.*, 486 F. App'x 186, 191 (2d Cir. 2012) ("Because the[] alleged instances of misconduct are not independently anti-competitive, we conclude that they are not cumulatively anti-competitive either."); *see also City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 928-29 (2d Cir. 1981) ("[W]e reject the notion that if there is a fraction of validity to each of the basic claims and the sum of the fractions is one or more, the plaintiffs have proved a violation of section 1 or section 2 of the Sherman Act."). Because none of the three components of the "elaborate, multi-part" scheme alleged in the Complaint could alone suffice to state an antitrust claim, the Court should reject Plaintiffs' attempts to conjure liability merely by mixing them together.

B. Insofar As The Antitrust Claims Are Premised On An Unlawful Contract, Combination, Or Conspiracy, Those Claims Must Be Dismissed Because The Complaint Does Not Allege A Unity Of Anticompetitive Purpose

Section 1 of the Sherman Act proscribes every "contract, combination . . . or conspiracy, in restraint of trade or commerce." 15 U.S.C. § 1. Counts II and III are alleged to arise under Section 1, and the individual state antitrust statutes each contain analogous provisions. To establish a violation of Section 1, "proof of joint or concerted action is required; proof of unilateral action does not suffice." *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 183 (2d Cir. 2012). The mere existence of a contract between two or more parties is insufficient. Rather, the plaintiff must allege "a plurality of actors agreeing to restrain trade." *Int'l Distrib. Ctrs., Inc. v. Walsh Trucking Co.*, 812 F.2d 786, 794 (2d Cir. 1987) (emphasis omitted). In other words, the allegations "must reveal a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful agreement." *In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d 671, 681 (S.D.N.Y. 2012) (Cote, J.) (quoting *Monsanto Co.*, 465 U.S. at 764).

A 2014 decision from the District of New Jersey applied these principles to a set of virtually identical facts. In *Mylan Pharmaceuticals v. Celgene Corp.*, No. 14-cv-2094, 2014 WL 12810322 (D.N.J. Dec. 23, 2014), the defendant held the rights to two brand name drugs. *Id*. at *1. The plaintiff desired to develop generic forms of the drugs, but alleged that it could not obtain samples because the defendant had entered into agreements with its distributors and with pharmacies that prevented them from selling the drugs to the plaintiff. *Id*. at *6. The plaintiff brought Section 1 claims on grounds that the defendant's commercial agreements with the distributors and pharmacies restrained trade by preventing generic competitors from filing ANDAs. *Id*.

As the district court recognized, however, while the plaintiff had alleged the *existence* of agreements between the defendant and the distributors and pharmacies, the plaintiff did not allege that the distributors or pharmacies "shared [the defendant's] purpose . . . or that they had a common

anticompetitive goal." *Id*. at *8. In granting the defendant's motion to dismiss, the court observed that there were no allegations that the distributors or pharmacies "stood to benefit from the alleged anticompetitive scheme," nor even that they "had knowledge of [the defendant's] anticompetitive intent." *Id*. (emphasis omitted).

While Plaintiffs allege that Vyera entered into contracts with distributors and API suppliers, the Complaint contains *no* allegation that any of the distributors or API suppliers shared Defendants' alleged anticompetitive intent. To the contrary, the Complaint alleges that these counterparties were simply acting at Vyera's direction pursuant to their commercial contracts, and had no independent desire or incentive to harm prospective generic competitors. *See, e.g.*, Am. Compl. ¶ 100 (alleging that Vyera "*imposes* resale restrictions on all of its distributors" (emphasis added)), ¶ 101 ("None of Vyera's distributors is *allowed* to sell Daraprim to generic companies." (emphasis added)), ¶ 154 (alleging that Vyera's exclusive agreement "*forbids* Fukuzyu from selling pyrimethamine to anyone other than Vyera . . . in the United States" (emphasis added)). Moreover, as in the District of New Jersey's *Celgene* decision, there is no allegation that Vyera's distributors or API suppliers "stood to benefit from the alleged anticompetitive scheme," or even that they "had *knowledge* of [Defendants' alleged] anticompetitive intent." 2014 WL 12810322, at *8. Accordingly, insofar as Plaintiffs' claims arise under Section 1 of the Sherman Act, or are otherwise premised on an allegedly unlawful contract, combination, or conspiracy, they must be dismissed.

CONCLUSION

For the foregoing reasons, the Complaint must be dismissed in its entirety.

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Respectfully submitted,

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